Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Telephone: 847.680.1000
Facsimile: 847.918.3860

K013483
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JAN 1 4 2002

Pre lubricated Intermittent Catheter

Hollister

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor
Hollister Incorporated
2000 Hollister Drive
Libertyville IL. 60048

Contact Person
Joseph S. Tokarz
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847) 680-2849
Fax: (847) 918-3860

Date Summary Prepared – October 17, 2001

2. Name of Device:

InCare Pre lubricated Intermittent Catheters

3. Name of Predicate Device(s)

Self-Cath Plus by Mentor	K003784
InstantCath by MTG	K973120
MMG/O'Neil by Rusch	K010420
Self Cath CS by Mentor	K003873

4. Description of Device

The InCare Advance and Advance Plus Intermittent Catheters are pre-lubricated with gel to promote easy insertion and user convenience. The catheter gel is contained in an integral reservoir, which eliminates gel migration throughout the package. The InCare Advance and Advance Plus catheters are sterile, non-latex, polyvinyl chloride catheters. A unique manufacturing process ensures that the eyes of the intermittent catheters are polished and smooth to help eliminate trauma to the urethra, reducing the possibility of hematuria.

The catheter packaging has been designed to facilitate easy opening for those users with limited dexterity. Both catheters incorporate a no-touch design, which enables the user to easily insert the catheter without direct hand contact, thus reducing the possibility of contamination.

The InCare Advance Plus Intermittent Catheter has an introducer tip that is intended to reduce reoccurring UTI and a collection bag to contain urine. The InCare Advance Plus is also available in a kit known as InCare Advance Plus Kit.

The InCare Advance and Advance Plus pre-lubricated intermittent catheters are available in various sizes and with a straight or coude tip to accommodate a wide range of male, female, and pediatric end users.

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5. Statement of Intended Use

The InCare Pre lubricated Intermittent Catheters are indicated for use by male, female and pediatric patients for the purpose of bladder drainage. The Catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract.

6. Statement of Technological Characteristics of the Device

The InCare Pre lubricated Intermittent catheter is substantially equivalent to the predicate devices in design, materials used, and intended use. The InCare Intermittent Catheters are made of a PVC material that is substantially equivalent to the predicate devices.

Biocompatibility assessment of the InCare Pre lubricated Intermittent Catheters has been conducted based on the principles and guidelines established by various governmental regulatory agencies and standard setting organizations. Among these are the following: United States Pharmacopoeia, General program memorandum #G95-1, United States Food and Drug Administration Office of Device Evaluation and The International Standards Organization ISO 10993-1 Biological Evaluation of Medical Devices. Based upon the results of this assessment, the materials used to fabricate the InCare Pre lubricated Intermittent Catheters are considered biocompatible and appropriate for their intended use.

7. Conclusion

Based on information presented above and in the body of this premarket notification the InCare Pre lubricated Intermittent catheters are substantially equivalent to devices currently in distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2002

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
LIBERTYVILLE IL 60048-3781

Re: K013483
Trade/Device Name: Hollister InCare Prelubricated Intermittent Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Codes: 78 KOD and FCM
Dated: October 17, 2001
Received: October 18, 2001

Dear Mr. Tokarz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K013483
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b. Statement of Intended Use

510(k) Number (if Known): K013483
Device Name: InCare Pre-lubricated Intermittent Catheter

Indications For Use:

The InCare Pre-lubricated Intermittent Catheter is indicated for use by male, female and pediatric patients for the purpose of bladder drainage. The Catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids to or from the urinary tract.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter-Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Bergman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013483